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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,926	02/27/2002	Lixiao Wang	10527-395001 / 02-026	4859

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225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/083,926	Applicant(s) WANG ET AL.	
	Examiner (Jackie) Tan-Uyen T. Ho	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 19,37-42 and 44-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18,20-36 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/3/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The information disclosure statement (IDS) submitted on 1/3/05 is acknowledged and considered.

Claim Objections

2. Claims 6-9, 11-13, 23-29 are objected to because of the following informalities: "a distensibility" should be "a lower distensibility". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 10, 14, 15, 17, 18, 20-22, 32, 33, 35, 36 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Barath (5,196,024).

Barath discloses a medical device including: a balloon (2) having a first material (2), a second material/stripped portion (13), a cutting element (6) and striped portions. Wherein the portions including second material including cutting element inherently have distensibility lower than other portions.

In regard to claims 10, 20 and 43 are a product by process claims, the balloon as claimed does not include structure distinct from the prior art.

In regard to claim 16, the number of cutting elements is less than the number of striped portions (13, 15, 17).

Art Unit: 3731

In regard to claims 17 and 18, the striped portions (13 or 15 or 17) extend parallel to the longitudinal axis of the balloon and are equally spaced around the circumference of the balloon.

In regard to claims 21 and 32, the balloon is a multi-layered balloon (layers 2, 13, 15, 17) and comprises inorganic material.

In regard 33, 35 and 36, the cutting element is carried by the balloon centered over the striped portions (fig. 11).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6-9, 11-13, 23-31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barath (5,196,024). In regard to claims 6-9, 11-13, 23-29 and 34, although, Barath does not disclose the length of the striped portions as claimed, it is well known to adjusting the length of the striped portions in order to accommodate the cutting elements and it is known in the art to adjust the length of the cutting elements in order to provide a desired cutting surface on the balloon. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barath striped portions to accommodate certain size of cutting elements in order

Art Unit: 3731

to provide a desired cutting surface on the balloon for treating a certain area on a vessel wall.

In regard to claim 30, although Barath does not disclose the striped portion being made from a liquid crystal polymer, Barath suggests to make the strips from hard plastic. A liquid crystal polymer is a well-known material in the art to make angioplasty balloon portions that require rigid. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the material of the striped portion of Barath's balloon with a liquid crystal polymer in order to provide stiffness to a balloon portion to support the cutting element on the balloon.

In regard to claim 31, although, Barath does not disclose radiopaque markers on the balloon, it is well known in the art to provide visual makers or making the surgical components from radiopaque material in order to indicate the location of the surgical components at treated site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ colorant or radiopaque markers on the striped portions where the cutting element disposed in order to locate the cutting elements at the treated site and make a precise cut.

Response to Arguments

7. Applicant's arguments filed 12/16/04 have been fully considered but they are not persuasive. Applicants argue that Barath fails to disclose a first material surrounding a second material or stripes. Examiner disagrees. Barath disclose a first material surrounding a second material or stripes (Fig. 14).

Art Unit: 3731

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN or NGUYEN can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

March 6, 2005